

EXHIBIT A

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND
SOUTHERN DIVISION

ORIGINAL

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BAVARIAN NORDIC A/S, :
 : Case No. 06-2406
Plaintiff, :
 :
v. :
 :
ACAMBIS, INC., et al., : Greenbelt, Maryland
 :
Defendants. : December 13, 2006
- - - - - x

TELEPHONE CONFERENCE

BEFORE: THE HONORABLE CHARLES B. DAY, Judge

APPEARANCES:

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KEYNOTE: "----" Indicates inaudible in transcript.

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1 P R O C E E D I N G S

2 THE COURT: Okay. This is the case of Bavarian
3 Nordic versus Acambis, Case No. DKC-06-2406. And if I could
4 have counsel identify themselves for the record.

5 MR. LUBITZ: David Lubitz, L-u-b-i-t-z, on behalf
6 of Bavarian Nordic. Good morning, Your Honor.

7 MR. DUNN: And Jeff Dunn, D-u-n-n, of the Venable
8 firm, on behalf of Acambis, Your Honor. Good morning.

9 THE COURT: Good morning.

10 MR. FREDERICK: Good morning, Your Honor. Jim
11 Frederick, from the United States Attorney's Office, on
12 behalf of the National Institutes of Health.

13 MR. HOSKIN: Good morning, Your Honor. This is
14 Gary Hoskin, from the Department of Justice, Intellectual
15 Property Section. With me also is Erica Franklin of our
16 section. Also on behalf of NIH.

17 THE COURT: Okay. Thank you all.

18 MR. FREDERICK: Your Honor, this is Jim Frederick.
19 Just real briefly, Mr. Hoskin and his assistant there will be
20 handling the substance of this matter on behalf of the
21 Government.

22 THE COURT: Okay. Thank you. And if I am correct,
23 this is really a matter between Bavarian Nordic and the
24 Government, and I assume counsel for Acambis is really just
25 here for the ride?

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1 MR. DUNN: That is pretty much accurate, Your
2 Honor. We have an interest in it, but it is their motion.

3 THE COURT: Got you. Okay. Well, since it is the
4 motion of Bavarian Nordic, I will give you first and last
5 opportunity. I have -- in the interest of full disclosure, I
6 have reviewed all of the materials that the parties have
7 provided. I have looked at virtually all of the cases.

8 I certainly have my leanings going in, but I'm
9 having a hearing because, in fact, I want to make sure that
10 I'm right and I want to see if there is anything that I have
11 missed. And, this is your opportunity to move me off of
12 whatever dime I'm sitting.

13 So, Plaintiff, you get to go first.

14 MR. LUBITZ: Thank you, Your Honor. As the Court
15 is aware, Bavarian Nordic issued a subpoena in this matter,
16 dated July 24th. The subpoena asked for documents, as well
17 as testimony.

18 If the Court is amenable, I will discuss the
19 subpoena for documents first.

20 THE COURT: Okay.

21 MR. LUBITZ: The NIH has responded in this matter
22 by letter dated August 1st objecting to the production of
23 documents, as well as the production of individuals for
24 testimony. Bavarian Nordic then endeavored to have oral
25 discussions with the Government in an effort to try to come

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1 to some resolution of this matter.

2 And then, on September 1st, 2006, Bavarian Nordic
3 sent a letter to NIH narrowing the topics for the requested
4 documents, as well as for testimony. And NIH never replied
5 thereafter.

6 With respect to the subpoena for documents, NIH is
7 in violation of its own regulation, 45 CFR, Section 2.5
8 therein. The regulation requires NIH to treat the subpoenas
9 as subpoenas. So long as the subpoenas are legally
10 positioned, the Court has jurisdiction over them and --
11 and --

12 THE COURT: Properly served.

13 MR. LUBITZ: Properly served. That is right.

14 Thank you.

15 THE COURT: Okay.

16 MR. LUBITZ: Your Honor, can I just interject and
17 say that two of my colleagues, Robert Burdon and Crystal
18 Lynch, have joined me. But I will continue.

19 THE COURT: Okay.

20 MR. LUBITZ: So, in that regard, Your Honor, NIH
21 was required to respond with documents responsive to our
22 request, and they did not do so. They objected, citing
23 various grounds, but none of the grounds really go to the
24 sufficiency of the -- the legal sufficiency of the subpoena,
25 the proper service or this Court's jurisdiction. So, for

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1 that reason, we think there is a violation of the APA.

2 THE COURT: Let me ask a question. How is this
3 really different from say the classic civil dispute to when a
4 party files a request for discovery and they don't get proper
5 responses? One side decides to file a motion for a
6 protective order, and the other one decides a motion to
7 compel. Aren't they really just flip sides of the same
8 issue.

9 MR. LUBITZ: Well, there has been no motion for a
10 protective order filed by NIH in this case, and I would agree
11 with you that essentially, under the facts of this matter,
12 NIH is no different than a private party with respect to the
13 substance of the subpoena and the motion to compel.

14 THE COURT: Okay.

15 MR. LUBITZ: With respect to the subpoena for
16 testimony, it is true that NIH has objected saying that it is
17 not in its interest to comply with the subpoena for
18 testimony. But under the circumstances of this case, Your
19 Honor, we think it pretty clear that their decision also
20 violates the APA.

21 There is a material transfer agreement that NIH
22 entered into with Acambis holding NIH harmless and
23 indemnifying NIH. So, the idea that they are somehow liable
24 in this case is incorrect.

25 THE COURT: Let me ask a question. Does NIH face

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1 any exposure from any other litigant that may want to sue
2 them over this issue?

3 MR. LUBITZ: Well, I think not because of the
4 material transfer agreement. The provision of the material
5 transfer agreement is extremely broad, and I'm not aware of
6 any other parties who claim an intellectual property interest
7 in the MVA that is at issue in the underlying matter.

8 THE COURT: Well, let me be more direct. Is there
9 anything that would prevent Bavarian Nordic from bringing
10 direct suit against NIH?

11 MR. LUBITZ: Well, no. Not to my knowledge. I
12 mean, you -- you mean anything legally? Any legal --

13 THE COURT: Yes. Sovereign immunity would not
14 prevent that. Is that right?

15 MR. LUBITZ: Well, I think that -- well, sovereign
16 immunity, as this Court is aware, certainly applies in suits
17 against the government. I mean, it could affect perhaps the
18 forum. So, I mean, I don't know the degree to which
19 sovereign immunity would prevent Bavarian Nordic from suing
20 the government.

21 THE COURT: Okay.

22 MR. LUBITZ: But, in any event, with respect to the
23 subpoena for testimony, we also are confident that NIH has
24 violated 45 CFR, Section 2.1(b), which requires a policy of
25 strict impartiality on the part of NIH in suits between

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1 private parties.

2 Here in its letter objection to Bavarian Nordic NIH
3 has, on at least a couple of occasions, directly refuted some
4 of Bavarian Nordic's central allegations that are made in the
5 complaint here. And given the centrality of NIH's
6 participation in the receipt and transfer of the MVA virus to
7 Acambis, we think that the facts really are such here that it
8 requires testimony on the part of NIH officials.

9 THE COURT: Okay. Thank you. Let me swing around
10 to the Government.

11 MR. HOSKIN: Thank you, Your Honor. This is Gary
12 Hoskin. I guess -- well, first, as I understand it, Bavarian
13 Nordic is not addressing the testimonial aspect of it at all.
14 So, we are just dealing with the documents at this point.

15 THE COURT: I think that was his last argument.

16 MR. LUBITZ: That is correct, Your Honor. I am
17 addressing the testimonial portion.

18 MR. HOSKIN: Okay. As to the -- let me start
19 though with the testimonial portion because I think that is,
20 by far, the clearest. I think the Tuhey case directly
21 addresses that.

22 As to the ability of the Court to determine whether
23 it is really in the best interest of NIH to provide
24 testimony, we don't think that the Court is really in the
25 best position to do that. This is a type of decision that is

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1 really best left to NIH to determine what is in its best
2 interest and what is not.

3 THE COURT: Don't you really have to take, head on,
4 this question about the Vioxx decision?

5 MR. HOSKIN: Well, I don't think we do, Your Honor.
6 I think in this circuit the law is clear as to sovereign
7 immunity. Now, the Vioxx decision dealt with a totally
8 different question, and that is whether or not the Government
9 is a person, not whether the Government, even if a person,
10 has sovereign immunity.

11 We are not addressing the person part of it. Vioxx
12 may have viability certainly in the Fifth Circuit.

13 THE COURT: At least the Eastern District of
14 Louisiana.

15 MR. HOSKIN: Correct. But in this circuit
16 certainly Comsat is the controlling law. It says that the
17 Government does have sovereign immunity and that, therefore,
18 this is to be treated as an APA action and not under Rule 45.

19 THE COURT: I don't think anybody is disputing that
20 this is an APA issue. I think you are all on the same page
21 with that, and I agree.

22 MR. HOSKIN: And therefore, as a result of that,
23 the Vioxx issue of whether or not the government is a person
24 really falls away, since we are not dealing with Rule 45 and
25 whether or not it is -- the government can be a person under

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1 Rule 45.

2 THE COURT: Didn't the Vioxx decision go on to say
3 that the Court found that the refusal under the APA arbitrary
4 capricious standard was one which the FDA failed to get over,
5 and therefore, it was going to allow the depositions?

6 MR. HOSKIN: And we don't dispute that even under
7 Comsat that the government -- or that the Court rather has
8 the ability to reach the arbitrary/capricious standard. But
9 as we point out in our brief, there are some decisions and we
10 think this is one, that are really best left to the agency.
11 And it is really very difficult for a Court to come in and
12 say, well, this Court believes that the -- that the
13 Government's best interests are not in withholding testimony.

14 And I think that in real as -- that is exactly what
15 the Tuhey case stands for, the proposition that once a
16 government executive, a secretary of a department, has issued
17 orders, that those orders are to generally to be obeyed,
18 unless there can be a showing that they have violated their
19 own regulations, and we don't have that here. Certainly not
20 as to the testimony.

21 The question on the document side may be a little
22 bit different, but I will address that in a moment.

23 THE COURT: But in the Court's review of the
24 arbitrary/capricious question, isn't there a need for the
25 Court to look at the explanation offered by the Government

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1 and to see if, in fact, it fits with the context of the case?

2 MR. HOSKIN: Well, that is true, Your Honor. Well,
3 I don't think with the context of the case. I think the
4 question is whether the agency has determination -- is
5 arbitrary and capricious looking at the reasons that the
6 agency gave. You don't look at the case at all.

7 THE COURT: Well, I think we are saying the same
8 thing. It is one thing to say that we are not going to
9 release these materials because we don't like the way you
10 look. That would be arbitrary and capricious.

11 It is another thing to say we are not going to
12 release or allow someone to testify because we don't think it
13 is in our best interest.

14 MR. HOSKIN: That is correct, Your Honor.

15 THE COURT: So, if there is, I guess, a place for
16 the Court to at least look behind the label of saying we are
17 not going to allow this testimony under the Tuhey decision or
18 the Tuhey rationale, but then to say why is it that you are
19 not going to do so and does it at least pass, you know, the
20 laugh test?

21 MR. HOSKIN: Well, that is correct, Your Honor, and
22 I think you have to look at all of the reasons the agency
23 gave. I think in this case that goes a little beyond just we
24 don't want to do it because it is not in our best interest,
25 but I think that is certainly a central issue.

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1 Unless the Court has some other questions, I would
2 like to maybe move on to the documents.

3 THE COURT: Okay.

4 MR. HOSKIN: The first thing that I would like to
5 point out is if we go to Exhibit 9, which is this follow on
6 (sic) September 1st letter in which, I guess, Bavarian Nordic
7 complains now that they haven't received a response, I would
8 like to point out that the reason that they didn't receive a
9 response is that essentially the -- they sent the letter on
10 September 1st, which is the Friday before Labor Day.

11 The letter, on page 10, indicates that they intend
12 to file a motion the following week and are nonspecific as to
13 what day during that week. So, of four possible work days in
14 which they could file the motion, it could have been anywhere
15 from Tuesday to Friday.

16 I think it is -- and the letter itself is 10 pages
17 long.

18 THE COURT: But the motion wasn't filed actually
19 for another 13 days.

20 MR. HOSKIN: Yes. It was filed on the 14th, Your
21 Honor. But the expectation from the letter itself is that
22 the motion could be filed any time from the 5th to the 8th.

23 THE COURT: Well, wasn't that driven, in part, by t
24 he need to get this done before discovery closed on September
25 21?

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1 MR. HOSKIN: Well, it seems to be a little
2 disingenuous to wait until the last minute and then say you
3 have a lack of time. --- in which if they wanted to pursue
4 it, they could have gone ahead and pursued it with the
5 agency.

6 THE COURT: I thought the discussion was one in
7 which you all had some previous communications where they had
8 expressed an intent to narrow the discovery, the scope of the
9 request. Intervening along the way was the deposition. And
10 then right after that they say, okay, by the way, here is the
11 narrow request; let's talk about it or let's move forward.
12 And basically, it sounds like the Government disappeared.

13 MR. HOSKIN: Well, I wouldn't say that, Your Honor.
14 I think that you are requesting a response within one or two
15 days to a 10-page letter. It is a little unrealistic, to say
16 the least.

17 The fact that they waited another 11 days is --
18 certainly was their call, not the Government's. The
19 anticipation by NIH at least was that the -- or appears to be
20 that the letter, on its face, was saying that the motion was
21 going to be filed regardless.

22 You give a person one to two days to respond to a
23 10-day letter and then complain about it? I find that hard
24 to believe, Your Honor. But going to the merits, I think
25 there is an important point that is made in the response of

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1 NIH, and that is --

2 THE COURT: Before you get there, you have taken me
3 a good long way in terms of the unreasonableness, if you
4 will, of Bavarian to expect, I guess, an instantaneous
5 response. It is true that the letter says we expect you to
6 does. And let me find the language where it says we are
7 going to move to enforce the subpoena, which we will do next
8 week absent a response.

9 Well, you used the word earlier about call,
10 c-a-l-l. Maybe a call, an email note saying, hey, we have
11 got it, we are thinking about it, we will get back to you,
12 can we have more time? Why none of that?

13 MR. HOSKIN: I am not here to testify on behalf of
14 the agency as to what their motivation was or why it -- you
15 know, they did not respond sooner. You know, I think that --

16 THE COURT: They did not respond at all.

17 MR. HOSKIN: Especially if you look at the intent
18 of the letter. The last -- the next to last paragraph on
19 page 10, I'm not so sure that that is an offer of compromise
20 as it is essentially a threat; that if you don't react in the
21 next couple of days, we are going to file the suit anyway.

22 THE COURT: You may be right about that. Okay.
23 I'm sorry. I have slowed you down enough. Go right ahead to
24 the next issue.

25 MR. HOSKIN: Moving then to the -- it is actually

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1 the merits of their argument. I apologize for my cough, Your
2 Honor.

3 THE COURT: That is all right.

4 MR. HOSKIN: There has been no violation of the
5 regulation here, but I think an important point to note is at
6 the very beginning in the response of NIH they indicate that
7 they have already, in response to the ITC subpoena, which
8 they treated as a FOIA request -- they had already produced
9 essentially all of the documents that they had that they
10 would be willing to produce.

11 THE COURT: So that means you wouldn't be producing
12 any documents regarding the relationship between NIH and
13 Acambis that may have been the subject to this issue?

14 MR. HOSKIN: I believe that the indication is that
15 all documents -- remembering that the ITC case essentially
16 involves the same parties, was brought by Bavarian Nordic at
17 the same time, involves many of the same issues, or at least
18 the factual predicate for the issues are the same, the same
19 documents were produced; would have been produced.

20 THE COURT: I got the impression from Bavarian's
21 reply memorandum that the only thing that was produced was
22 basically what Bavarian already had, those documents relating
23 to the relationship between Bavarian and NIH. However, the
24 scope of their inquiries go beyond that and really are
25 talking about what is going on between Acambis and NIH with

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1 respect to this virus strain and the relationships.

2 Am I missing that? And I know you didn't have a
3 chance to file any kind of sur-reply or a rebuttal brief, but
4 that was the last word I had on that subject.

5 MR. HOSKIN: Well, I think, Your Honor, that the --
6 that much of -- I gather from -- in a sense, from NIH's
7 response; that whatever documents that BN believes that they
8 have would not have been produced in any event.

9 To the extent that -- I guess right now the issue
10 as framed is based on -- the only denial that we have is the
11 denial of the initial subpoena, which --

12 THE COURT: Is that --- not attached?

13 MR. HOSKIN: -- really the lack of information
14 provided and lack of a basis for requesting the information
15 from NIH. That is Exhibit 1, the two-page letter from BN.

16 Based on that letter and the denial of the request
17 from NIH, it is what this Court has -- it is how this Court
18 has to reach its decision. I think it is speculation, to
19 some degree, to try to determine what NIH would do if -- you
20 know, if it had proceeded and maybe if there had been further
21 discussions. That is something that maybe -- that there may
22 be some middle ground in, but that didn't occur.

23 We have the bare request for documents from BN. We
24 have the denial of that request based on essentially that the
25 documents have already been produced or -- or at least

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1 anything that would -- that the agency felt would be produced
2 had already been produced in the prior request.

3 And I think that actually answers, for the most
4 part, what -- you know, what Bavarian Nordic is seeking. I
5 mean, if that is all the agency would be giving them,
6 treating this again as a FOIA request since the Government is
7 not a party, then what are we really arguing about?

8 THE COURT: Is there anything to prohibit the
9 Government from being sued by Bavarian Nordic?

10 MR. HOSKIN: That is a difficult question, Your
11 Honor, because we have to speculate as to what Bavarian
12 Nordic's grounds for suit would be, and that is something
13 that I'm not really prepared to do. I think that -- I don't
14 know of any general prohibition against Bavarian Nordic suing
15 the United States, but obviously it would depend a lot on
16 what the allegations in any complaint would be.

17 And here, so far the only thing that Bavarian
18 Nordic has alleged is essentially some type of trade secret
19 violation, perhaps a violation of some kind of an agreement.
20 But the allegations are -- have never been actually framed
21 against the United States, and so I would really hesitate to
22 speculate as to how or what Bavarian Nordic believes that
23 they could bring against the United States.

24 THE COURT: Okay.

25 MR. LUBITZ: Your Honor, may I reply to some of the

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1 points made by counsel?

2 THE COURT: Yes. It is your motion. So you get
3 the last word.

4 MR. DUNN: Your Honor?

5 THE COURT: Yes?

6 MR. DUNN: Jeff Dunn. I would like to offer just
7 one or two observations, if I could. I don't know whether
8 you want that before or --

9 THE COURT: I probably should not, in the sense
10 that really the briefing is between the Government and
11 Bavarian Nordic. I suspect that you have got more knowledge
12 about this than I could ever hope to have. I probably should
13 limit it to these two on the record.

14 MR. DUNN: That is fine, Your Honor.

15 THE COURT: Okay. But thank you so much.

16 MR. LUBITZ: Your Honor, first of all, with respect
17 to the sequencing of events in this matter, I just also want
18 to point out that there was a certificate of conference of
19 counsel that was filed with our motion to compel in which it
20 is noted that after we sent our September 1st letter to NIH
21 we then followed up with a phone call on September 11th
22 explaining to them that we would file suit unless we could
23 come to a resolution of this matter.

24 So, I think the idea that Bavarian Nordic has not
25 gone as far as it possibly could go to try to resolve this

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1 matter short of litigation is incorrect. I mean, just sort
2 of taking a step back, you have got a subpoena, you have got
3 an objection, you have got a series of phone calls of counsel
4 for Bavarian Nordic to NIH.

5 After those series of phone calls you have got a
6 September 1st letter. Still no response from NIH. And then
7 you have got a final phone call from counsel for Bavarian
8 Nordic. So I think that the -- the idea that somehow
9 procedurally Bavarian Nordic has not done everything it
10 possibly could before putting this issue before the Court is
11 just not correct.

12 With respect to the documents and the ITC
13 proceeding, I think it is -- it should be pretty clear, as a
14 matter of law, that a FOIA response is less than what ---
15 might be entitled to under Rule 25. And for support of that,
16 Your Honor, I think I can just point you to the Federal
17 Register cite from our reply brief. That is 68 Federal
18 Register 25-838, which is the final rule of promulgating
19 amendments to 45 CFR Part 2.

20 And in that Federal Register cite NIH, or the
21 Department of Health and Human Services itself, notes that --
22 I will quote it. It says, "These amendments -- I'm going to
23 quote the paragraph that surrounds the phrase that I cited in
24 my reply brief.

25 "These amendments are designed to address cases in

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1 which a federal court has jurisdiction to issue a subpoena
2 for DHHS documents. In such cases the current regulation may
3 infringe on the power of the Court by allowing greater
4 authority to withhold a document under the FOIA than would be
5 the case under the rules governing the disclosure of
6 documents in court." Then it cites the Supreme Court case of
7 FTC against Grover, Inc.

8 It says it is not the intention of the department
9 "to create or broaden a federal litigation privilege through
10 this part. We are amending the regulation to limit the
11 applicability of FOIA to situations in which the issuing
12 tribunal has no jurisdiction over the department."

13 It should be pretty clear that NIH needs to go back
14 and look at its documents to see whether there are ones that
15 we are entitled to under the subpoena that is before this
16 Court. NIH, in responding to the ITC issued subpoena,
17 asserted that the ITC did not have jurisdiction over it, and
18 therefore, was treating that subpoena pursuant to FOIA.

19 THE COURT: Well, let me slow you down and see if I
20 understand the Government's position on this just a tad.
21 Didn't the Government say somewhere in its briefing that you
22 never provided the Court with the right subpoena to pursue
23 this at this time?

24 MR. LUBITZ: Well, I think the Government said
25 that, and we didn't provide the ITC subpoena, but we are not

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1 asking the Court to rule on the ITC issued subpoena.

2 THE COURT: I gather that. I thought that they
3 were saying that you did not provide the right subpoena in
4 this case. But did you do so in your submissions? Was that
5 Exhibit No. 1 or 2?

6 MR. LUBITZ: Yes, Your Honor.

7 THE COURT: Okay. Let me hear from the Government
8 on that point.

9 MR. HOSKIN: No. I don't think that is the
10 argument that we made, Your Honor.

11 THE COURT: You are saying that they subpoenaed NIH
12 and they should have subpoenaed Dr. Moss?

13 MR. HOSKIN: Well, no. There are several different
14 subpoenas out here, and I think that the -- there is an
15 argument made by BN relating to the subpoena to Moss and our
16 efforts to limit Dr. Moss' testimony consistent with Tuhey.

17 Now, BN makes a fairly extended argument relating
18 to the Moss deposition and what occurred at that deposition.
19 Our argument was that none of that is relevant to this issue
20 because that was a separate subpoena and Tambian has never
21 raised the legitimacy of the Government's actions in that
22 subpoena as being improper or -- you know, in any way.

23 THE COURT: Let me shape the question so I can
24 understand better this point. I am looking at Exhibit 1 that
25 was attached to the Plaintiff's motion.

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1 MR. HOSKIN: Correct, Your Honor.

2 THE COURT: Okay. Are you with me?

3 MR. HOSKIN: That is a subpoena to NIH.

4 THE COURT: This is a subpoena for the documents
5 that we are arguing about in part here today. Correct?

6 MR. HOSKIN: That is correct.

7 THE COURT: Okay. This is the subpoena to which I
8 don't believe the Government has ever suggested that it was
9 legally insufficient or that it was improperly served or that
10 the Court didn't have authority. Is that right?

11 MR. HOSKIN: The first two are correct. We have
12 not disputed that it was -- the service. Well, I guess to a
13 certain degree the legal sufficiency or the jurisdiction or
14 the question because of the Government's sovereign immunity.

15 THE COURT: Was that raised in your papers?

16 MR. HOSKIN: Excuse me?

17 THE COURT: Was that raised in your papers?

18 MR. HOSKIN: Yes, Your Honor. I believe it is.

19 THE COURT: Take me there again.

20 (Pause.)

21 MR. HOSKIN: Page 12, Your Honor. The ---
22 paragraph begins, "Although NIH responds, it does not
23 specifically articulate counsel's conclusions."

24 THE COURT: Yes. I have that highlighted with a
25 question mark beside it. So, give me just a moment.

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1 (Pause.)

2 THE COURT: And for some reason you think that
3 because you are not a party to the litigation that this
4 subpoena, under Rule 45, is barred. Under Comsat? Is that
5 where you are at?

6 MR. HOSKIN: Yes. Our argument is that under NIH's
7 own regulation and in light of Comsat that the NIH was only
8 required to treat the subpoena as a request under FOIA.

9 THE COURT: I thought that came under the
10 regulation cited Title 45 CFR 2.5(b). Sub 'b' says if it is
11 legally insufficient, improperly served or the Court doesn't
12 have jurisdiction, then the subpoena shall be deemed a
13 request under FOIA. What am I missing? Obviously something
14 is going on.

15 MR. HOSKIN: I am not sure that you are missing
16 anything, Your Honor. I think that the -- there is
17 essentially a tension here because of the Government's
18 sovereign immunity, and -- so how you can serve a subpoena
19 that is enforceable against the Government when it is immune
20 is the question.

21 The Comsat case and NIH's own regulations certainly
22 provide for providing documents; treating any subpoena as a
23 FOIA request and providing documents.

24 THE COURT: Any subpoena or only subpoenas that are
25 in some way defective.

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1 MR. HOSKIN: Right. Or over -- where the Court
2 does not have jurisdiction over the party.

3 THE COURT: Correct. Okay.

4 MR. HOSKIN: And in this case it is our contention
5 that the Court does not have jurisdiction over the Government
6 because of sovereign immunity.

7 THE COURT: Because you are not a party to the
8 litigation?

9 MR. HOSKIN: Exactly. May I reply to that point?

10 THE COURT: Just a moment. I want to make sure I
11 grasp it all though, and I think I need counsel now to take
12 me to Comsat and to highlight that language for me again.
13 I'm looking myself, and maybe I'm just missing it, because
14 Comsat was dealing with an arbitrator's subpoena, not a court
15 subpoena.

16 MR. HOSKIN: That is true, Your Honor.

17 (Pause.)

18 MR. HOSKIN: I think it is the portion --

19 THE COURT: Take your time.

20 MR. HOSKIN: We address at length in the standard
21 of review section, starting on page four.

22 THE COURT: I wasn't so much looking at your
23 memorandum, but I will go back there. Give me a second.
24 Standard review. I have got it. And you cite page 274 of
25 the Comsat decision.

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1 MR. HOSKIN: Correct.

2 THE COURT: Let me turn to page 274. "When the
3 Government is not a party, the APA provides the sole avenue
4 of review of an agency's refusal to permit its employees to
5 comply with subpoenas. I read that as testimonial subpoenas.
6 Am I missing something?

7 MR. HOSKIN: If I may have just a moment, Your
8 Honor.

9 (Pause.)

10 MR. HOSKIN: That is dealing with testimonial
11 subpoenas. That is correct. But I think that there is also
12 a statement I have referenced on 277.

13 THE COURT: Okay. Give me a second. Let me find
14 my place.

15 (Pause.)

16 THE COURT: 277. I'm there.

17 MR. HOSKIN: I don't have the exact quote, Your
18 Honor, but I had cited it as saying that sovereign immunity
19 generally permits the federal government to refute compliance
20 with a third party subpoena.

21 THE COURT: I think that language is reflected in
22 the next to the last paragraph of the decision under subtitle
23 three where it says "in summary" and then maybe a couple of
24 sentences therein. I have been reading that to talk about
25 the testimonial portion as opposed to documents.

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1 MR. HOSKIN: Your Honor, I think that -- the
2 difference -- the only real difference between these
3 situations, between testimony and documents, is that the
4 government generally has waived a certain degree of sovereign
5 through FOIA for documents. There is a set statutory
6 procedure which obviously even if the -- if there is
7 absolutely no jurisdiction of any court over the government,
8 any citizen could come in and request documents.

9 The regulations essentially account for that by
10 setting up one procedure for documents and one procedure for
11 testimony of employees. I think that is why there may be a
12 little bit of a confusion here. The rules generally apply --
13 in terms of jurisdiction and sovereign immunity apply to the
14 government as a whole, and it shouldn't make any difference
15 as to whether it is documentary or testimonial, but for the
16 fact that FOIA exists and we always have to account for FOIA.

17 And that is what the NIH's own regulations attempt
18 to do. It sets one standard for testimony where FOIA would
19 not apply in any event, and a separate standard then for
20 documents where even if the subpoena is insufficient, the
21 agency would comply with what it would ordinarily have to
22 comply with anyway, which is the FOIA standard.

23 THE COURT: Give me a moment.

24 (Pause.)

25 THE COURT: Okay. Let me hear further from

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1 Bavarian.

2 MR. LUBITZ: Your Honor, first of all, the waiver
3 of sovereign immunity, of course, is subject to the APA,
4 which provides for an arbitrary, capricious and contrary to
5 law standard of review. The government and NIH are subject
6 to Rule 45. If you look at both the Vioxx decision and the
7 recent D.C. Circuit decision that I cited, I think it should
8 be pretty clear that the government is a person under Rule
9 45.

10 In addition, the regulations -- NIH's own
11 regulations provide that FOIA is only applicable where a
12 party sends something to the government that should not be
13 construed as a subpoena. That is not the case here. The
14 regulations themselves provide that so long as the Court has
15 jurisdiction, so long as the subpoena is legally sufficient
16 and so long as service is proper, that NIH is supposed to
17 treat that subpoena as a subpoena.

18 THE COURT: So, is it your position that Comsat's
19 language, with respect to federal of civil procedure 45 where
20 it says in the last paragraph that the District Court erred
21 in enforcing the arbitrator's subpoenas, the Court also erred
22 when it reviewed the government's actions under Rule 45
23 rather than the APA, that that really is only triggered
24 because the arbitrator did not have appropriate authority to
25 issue the subpoena?

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1 MR. LUBITZ: I think that is one point. But I
2 think the other point is that what Comsat stands for is that
3 the subpoenas themselves, when the government is not a party,
4 should be reviewed under the APA's arbitrary, capricious and
5 contrary to law standard. And, of course, Rule 45 has a less
6 onerous undue burden standard, at least from the perspective
7 of the subpoenaing party, leaving that as the critical point
8 that Comsat was making.

9 THE COURT: Well, if your position is true, then it
10 all comes full circle with respect to an analysis as to
11 whether or not the government's action here was arbitrary and
12 capricious.

13 MR. LUBITZ: Yes.

14 THE COURT: I'm sorry? I couldn't hear you.

15 MR. LUBITZ: Yes.

16 THE COURT: Okay. And you bear the burden of proof
17 on that, and that is what you have set forth, at least your
18 position, in your papers. Is that right?

19 MR. LUBITZ: Yes. Yes. So, the idea that this
20 Court has no jurisdiction because the subpoenas are
21 unenforceable pursuant to Rule 45 I think is incorrect.
22 These subpoenas with respect to the documents pass the test
23 under 45 CFR, Section 2.5(a), and the government was obliged,
24 or NIH was obliged, to treat these as subpoenas for
25 documents.

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1 And they violated their own regulations, and in
2 doing so they violated the APA's arbitrary and capricious
3 standard.

4 THE COURT: Okay. I understand where you are
5 coming from.

6 MR. LUBITZ: Okay. And then, with respect to the
7 testimony of -- to pick up on your analogy, Your Honor, you
8 said that if NIH had said, well, we are not going to enforce
9 this subpoena because we don't like the way you look, that
10 that would be arbitrary and capricious. I think everybody
11 agrees with that.

12 I think if NIH further said we are not going to
13 enforce these subpoenas because we think it is not in our
14 best interest because we don't like the way you look, this
15 Court would also be obliged to hold that NIH's determination
16 that it wasn't in its own best interest to enforce the
17 subpoena is arbitrary and capricious and contrary to law.

18 And, in effect, that is what NIH has done with
19 respect to the subpoena for testimony. The reasons that they
20 have given as to why they refused to permit their employees
21 to sit for testimony are arbitrary, capricious and contrary
22 to law. They violate the section of the regulations that
23 require strict impartiality and the reasons -- when you look
24 at the context of this particular case with the fact that
25 there is a material transfer agreement here, as well as a

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1 protective order, a two-tier protective order in place, they
2 don't hold water. They are arbitrary and capricious.

3 THE COURT: Aren't they saying in both instances,
4 and haven't they said in both instances, that the reason we
5 are not going to do this is because you are going to make us
6 look bad?

7 MR. LUBITZ: Yes. And that is an arbitrary and
8 capricious reason.

9 THE COURT: At least under the Vioxx decision it
10 is.

11 MR. LUBITZ: Yes. And not only that, but if you
12 look at the housekeeping statute here, if you look at the
13 Project Bioshield legislation here, all of those are
14 different components of showing that that reason is arbitrary
15 and capricious.

16 THE COURT: Okay. Thank you. Let me hear further
17 from the Government.

18 MR. HOSKIN: Just a couple of points, Your Honor.
19 First, the reason that the agency withheld testimony is not
20 because they would look bad, but because they would not have
21 an adequate ability to defend themselves and their employees.

22 THE COURT: Defend yourself from no lawsuit?

23 MR. HOSKIN: Well, we wouldn't be a party. And as
24 we point out in the brief, Bavarian Nordic's attorneys, even
25 at the deposition, tried to prevent government counsel from

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1 presenting any objections during the testimony.

2 THE COURT: I think it was just the opposite. It
3 was government attorneys who were preventing Bavarian Nordic
4 counsel from discovery, and be that right or be it wrong,
5 they were the ones there who were there to protect their own
6 interests. And I'm still struggling with if it is not about
7 a lawsuit, what is the interests that the government is
8 trying to protect that they cannot protect?

9 MR. HOSKIN: Well, --- party to the lawsuit. We
10 could seek our own testimony. We could seek discovery from
11 the other parties. We could show what the weaknesses of
12 their arguments are and --

13 THE COURT: Let me try differently. If the
14 government is not being blamed, what is it that the
15 government -- and if the government has no fear of being
16 sued, what is the need for the government to protect
17 anything?

18 MR. HOSKIN: Well, we are being blamed. That is
19 the whole point. Acambis hasn't been accused of any
20 wrongdoing, but the NIH employees have been.

21 THE COURT: Acambis is being sued. Acambis is
22 being sued. There is a formal charge against Acambis, be it
23 right or be it wrong. You are being -- at least your
24 employees are being subpoenaed to provide testimony.

25 Now, when I say it is one thing to talk about

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1 having blamed in a non-legal sense. If the theories that are
2 lined just beneath Bavarian Nordic's action here hold true,
3 then what they are really saying is Acambis may have done
4 something wrong, but guess what? The folks over at NIH,
5 including Dr. Moss, did something terribly wrong as well.
6 They breached the contract and all these other things.

7 Well, if those other things never grow up to be a
8 lawsuit or if the government never has exposure directly,
9 regardless of indemnity or anything else, if they could never
10 be sued by Bavarian Nordic or anyone else on this action,
11 what is the interest, the legal interest, that the government
12 needs to protect by being a party opponent.

13 MR. HOSKIN: If all of those things were true, Your
14 Honor, there would be no need.

15 THE COURT: Okay. So what is it?

16 MR. HOSKIN: That is the question, is whether any
17 of those things are true, and that is the problem that we
18 face. The allegations are made in a lawsuit in which we have
19 no ability to take discovery, no ability to defend the
20 government or its employees and, to a certain degree, that
21 after BN gets done with its suit with Acambis, that it won't
22 file suit against the government.

23 THE COURT: That is the interest then.

24 MR. HOSKIN: That it won't use the very discovery
25 it got as a basis for another lawsuit against the government.

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1 THE COURT: Well, that would be the legal interest
2 that I think you have been hinting around that you have some
3 exposure on.

4 MR. HOSKIN: Well, certainly that is a possibility.
5 The trouble is we don't know right whether we have exposure
6 or not because Bavarian Nordic essentially is playing games
7 out here.

8 THE COURT: Okay. I appreciate the fact that there
9 may be the potential for a lawsuit. Whether it is in reality
10 or not, you don't know sitting where you are today, and there
11 is nothing wrong about that analysis.

12 But in the event -- let's assume there was a law
13 out there that says the government cannot be sued by Bavarian
14 Nordic on this claim or anything related to it, I don't know
15 that the government has a need to protect any other interests
16 by being a party litigant. And if I'm missing -- I'm trying
17 to figure out if there is something else aside from the
18 potential of a lawsuit that the government is concerned
19 about.

20 MR. HOSKIN: Well, --

21 THE COURT: Why else would you take depositions?

22 MR. HOSKIN: Well, I guess if there was no
23 possibility of a lawsuit against the government or its
24 employees for their actions in the course of their
25 employment, then that would be true. Unfortunately, such a

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1 law just does not exist.

2 THE COURT: Okay. Fair enough?

3 MR. LUBITZ: Your Honor, may I just make two
4 points?

5 THE COURT: Well, you were promised the last word.
6 So, go ahead.

7 MR. HOSKIN: Before he does, Your Honor, I have one
8 other point I would like to make.

9 THE COURT: Okay. I am going to give him the last
10 word. So, you slip in now while you can.

11 MR. HOSKIN: One of the -- I think one thing that
12 may have been lost in the discussion here is that one of the
13 very significant reasons for denying the subpoena, or the
14 production under the subpoena, was NIH's determination that
15 the request failed to comply with the regulation, and I think
16 that is an important point that the Court should look at.
17 That is all I have, Your Honor.

18 THE COURT: How did it fail to comply?

19 MR. HOSKIN: Well, particularly that the
20 information requested was not otherwise available from
21 another source. Most of the information that was requested
22 is stuff that either BN should have in its own possession or
23 people like Dr. Mayer or its -- or co-plaintiff should know
24 because he was a party to the discussions. Information that
25 was already available from Acambis or from other sources,

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1 such as the information previously supplied to the ITC
2 subpoena.

3 THE COURT: Well, let me try it like this. I
4 haven't taken the time to look through or commit to memory
5 all of the various topics and issues attached to this
6 subpoena. I'm looking at -- just say question number 11.
7 "All documents concerning any steps taken by NIH to isolate
8 individuals at NIH who received or are exposed to
9 confidential information from Bavarian Nordic."

10 Are you telling me that information has been
11 provided in the FOIA request or would have been provided?

12 MR. HOSKIN: Well, no. I think that the point that
13 I am trying to make here, Your Honor, is that as to each one
14 of these requests Bavarian Nordic did not indicate why that
15 information was not available from another source. It
16 implied the only place they could go was the government.

17 THE COURT: Wasn't that the subject of the letter
18 that they wrote to you?

19 MR. HOSKIN: Well, their response to NIH was the
20 September 1st letter which, of course, became water under the
21 bridge as soon as this action was filed. But even in that
22 letter, Your Honor, all they did is say, well, it is not
23 available from other sources.

24 For instance, with Dr. Mayer in particular they
25 say, well, because we don't know essentially what the NIH

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1 would say about Dr. Mayer; discussions with NIH. That is not
2 the question. It is what -- certainly you may not have
3 complete information in the sense where you are talking about
4 discussions that each and every person may have a different
5 point of view. That is not the question.

6 The question is whether the information is
7 available from another source, and in each one of these cases
8 the regulation requires that the first requestor provide
9 information as to why they can't get the requested
10 information from a different source.

11 THE COURT: Okay. Let me ask it this way. Let's
12 go down to number 22. They asked for NIH policies regarding
13 employment and consulting agreement between NIH employees and
14 third parties. What would be the other source of information
15 there?

16 MR. HOSKIN: Your Honor, again, I think we are
17 reversing the question.

18 THE COURT: Okay. I understand that they have a
19 burden to tell you why they can't get it. I am assuming to
20 some degree that was articulated in the letter of September
21 1, 2006. This question, standing on its face, would give one
22 great reason to think that they have this information in
23 their possession, nor would they have legal, reasonable means
24 to obtain.

25 It is like asking you what do you do in-house. And

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1 it talks about third parties with no indication of who these
2 third parties may be. You are telling me they need to tell
3 you something else to respond to this question other than we
4 don't know and we don't know where to find it?

5 MR. HOSKIN: I think -- certainly there is -- to
6 the extent that that also requests documents, I'm not sure
7 that that hasn't already been answered, in the sense that it
8 may have been produced already. And certainly I think some
9 of these requests may be --

10 THE COURT: I accept your position with respect to
11 the information they could or should be able to obtain from
12 either Acambis or their own in-house experts, be it Professor
13 Mayer or whoever else.

14 But it seemed to me, just glancing at this request,
15 that there were some things in there that were certainly
16 beyond their ability to go fetch from some other place.

17 MR. HOSKIN: And certainly some of those are also
18 answered by the other objections, which is not in the
19 interest of NIH. But at the end of the day there perhaps are
20 some documents which the government would be willing to
21 produce in response to a request where the -- Bavarian Nordic
22 comes in and says, yes, these are the few times that we just
23 cannot get anywhere else and narrow it down that way and
24 provide the government with some -- either some basis or --
25 and certainly some of these -- you know, we have got a forest

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1 of requests here and one tree that -- or maybe two trees that
2 have some validity.

3 THE COURT: I love that analogy. I am going to
4 steal it and use it somewhere else.

5 MR. HOSKIN: Thank you. I would be honored.

6 THE COURT: Is that to say that if their September
7 1st letter had come in and given you a longer window to
8 respond, that there may be something out there that may be
9 worthy of a response?

10 MR. HOSKIN: I think in terms of the document
11 request that is certainly the case. Now, part of the problem
12 here is the -- Bavarian Nordic has mentioned the September
13 11th conference, and I think there is a bit of debate here as
14 to whether that was really an attempt to settle or whether at
15 the end of that conference the government was essentially
16 told this is the end, we are filing suit and as a result of
17 that took no further action.

18 THE COURT: Okay. I can appreciate that. I think
19 the point that was being made by Mr. Lubitz at that point was
20 that the letter of September 1 wasn't the last communication.
21 By the way, we picked up the phone on the 11th and we were
22 still seeing if something was coming, and it wasn't.

23 It very well may be, from your perspective at
24 least, that at the end of that discussion on the 11th this
25 was a matter headed for the courthouse steps.

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1 MR. HOSKIN: Right. And certainly I think it is a
2 matter of common experience too, at least for -- in the sense
3 that it is well known that once it becomes a matter in
4 litigation then the agency turns it over to the Department of
5 Justice, and we are the ones that are responsible for all
6 actions thereafter.

7 So, yes. It is not -- or it is not a case, one way
8 or the other, that the government is in any way attempting to
9 avoid answering. It is a matter of reality, that once we are
10 notified that it is going to be in litigation, you know, it
11 gets transferred. It comes down to the Justice Department or
12 out to the Assistant United States Attorney, or the United
13 States Attorney's Office, and we are the people that become
14 the lawyers.

15 THE COURT: Well, to the extent that I have a
16 criticism on the exchange here and the procedure between the
17 parties following this September 1 letter, it is that I think
18 the government should have done more. I don't think that
19 they should have read that letter, which said we are going to
20 do something if we haven't heard from you by next week, as
21 saying we have only got a couple of days.

22 Granted, it is on the tail of a long holiday
23 weekend, but I think to the extent of the parties trying to
24 move these things along, picking up the phone or sending an
25 email note, particularly in light of the extensive activity

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1 that was occurring within the five to seven days before then,
2 and particularly with the pendency of this close of discovery
3 on this basically out of district litigation, to just sit and
4 do nothing; I think there is a better practice out there.

5 I shouldn't say anything more stronger than that.
6 I just wish that we could have handled this a little bit
7 differently, and you obviously perceived it in a little
8 different way.

9 MR. HOSKIN: Well, no, Your Honor. I understand
10 what you are saying, but I think certainly the -- we also
11 have to be aware that this was a very limited amount of time.
12 And as you point out, it is a 10-page letter.

13 There is no actual even "respond by a certain
14 date." It is just kind of hidden in at the end of the
15 letter. That was my only point, Your Honor. I don't think
16 that it is that unrealistic, given the time frame, that the
17 government didn't respond.

18 And certainly there is always room for hope that we
19 could respond better or that we should respond quicker, but
20 these are large organizations and it takes time sometimes
21 just to get the request to the large person. And over a
22 holiday weekend, that person may not even be there.

23 THE COURT: All right. Thank you, Mr. Hoskin. I
24 promised Mr. Lubitz I would give him another shot. I assume
25 Mr. Dunn is still awake?

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1 MR. DUNN: Yes, Your Honor. It is hard to keep my
2 mouth shut, but I'm following your guidance.

3 THE COURT: Okay. Well, thank you, sir, and I
4 appreciate your patience with us.

5 Mr. Lubitz, your last shot.

6 MR. LUBITZ: Thank you, Your Honor. Let me just
7 point out first that seven weeks elapsed between the date of
8 the subpoena that Bavarian Nordic served on NIH and the date
9 that Bavarian Nordic filed suit in your court. During those
10 seven weeks there was a single response from the government.

11 On the side of Bavarian Nordic there was a 10-page
12 letter, as has been extensively discussed, as well as two
13 sets of phone calls.

14 With respect to the September 1st letter and the
15 allegation by the government here that somehow we haven't
16 explained how we can't get these documents and testimony
17 topics from anywhere else, I think the letter, Exhibit 9 to
18 our motion to compel, goes into great detail on each topic
19 narrowing -- eliminating some topics and narrowing others.

20 I think, to continue the analogy, if there was a
21 forest, I think that there are now, by virtue of Exhibit 9,
22 the important select trees that are at issue here and all of
23 them are important. And the ways in which Bavarian Nordic
24 needs the information from the government is explained in
25 detail in Exhibit 9.

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1 THE COURT: My goodness. I am starting to feel
2 like a park ranger.

3 MR. LUBITZ: Well, in Greenbelt I think you have
4 probably got some more trees than we do here.

5 THE COURT: Okay.

6 MR. LUBITZ: Thirdly, with respect to the issue
7 about any legal liability on the part of NIH, I want to
8 emphasize the broad nature of the release from liability that
9 the government negotiated with Acambis. That is at Exhibit
10 3, paragraph 11 I believe, which is attached to our motion to
11 compel.

12 There is an indemnification provision and there is
13 a hold harmless provision.

14 THE COURT: Does that really help them? I mean, it
15 saves them from any suit brought by Acambis, but it doesn't
16 mean that they don't have to deal with a lawsuit.

17 MR. LUBITZ: Well, but I think it holds them
18 harmless. I am just going to take a look at paragraph 11 and
19 just quote it. "Recipient agrees to indemnify and hold
20 harmless the United States Government from any claims, costs,
21 damages or losses that may arise from or through recipient's
22 use of materials or commercial products."

23 THE COURT: That still doesn't mean that the folks
24 at NIH have to go over to a two-week trial as defendants.

25 MR. LUBITZ: Well, I think that the fact is that

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1 Acambis would -- if there were a two-week trial and there
2 were a verdict and if NIH -- that Acambis might well be
3 liable.

4 THE COURT: That may be if NIH is liable. But at
5 the end of the day NIH is still looking at headlines. Their
6 professor does something wrong and the U.S. Government looks
7 bad, even though Acambis may be footing the bill at the end
8 of the day.

9 MR. LUBITZ: Well, again, Your Honor, I think it
10 goes back to the point made by you and by the Vioxx court,
11 that truth is not a bad thing, especially in light of the
12 fact that there is no legal liability here on the part of
13 NIH.

14 The last point that I just want to make is if the
15 government truly was concerned here about its ability to
16 participate in discovery, it could look at Federal Rule 24
17 and look at the question of intervention.

18 THE COURT: I somehow thought you would save that
19 last little bit there. Okay. Yes. They do have
20 intervention powers possibly. Okay.

21 Well, you all have been very helpful in educating
22 me and, hopefully, moving along my analysis of this case. I
23 am going to review some of my notes on this and try to give
24 you some kind of rambling analysis of where I think this
25 matter comes out.

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1 It is not my intention to issue a detailed written
2 memoranda on this point. So, this record is basically what
3 the parties will be referred to, to the extent that you have
4 a need to come back to it. Of course, it will be on file
5 with the Clerk's Office, and you are free to order
6 transcripts or whatever you needs may be to be addressed.

7 There is no dispute that Bavarian Nordic provided
8 technology to NIH, and this is all about an effort to develop
9 some better smallpox vaccine in compliance with some federal
10 programs. And we have got RSPs out there and the Defendant,
11 Acambis, and the Plaintiff, Bavarian Nordic, were awarded
12 contracts, and I assume that one was still pending at the
13 time of the filing of Plaintiff's motion.

14 But the Plaintiff contends that it gave this
15 technology to NIH under two non-disclosure agreements on
16 December of 2000 and February of 2001. Parenthetically. I
17 don't recall seeing such agreements and certainly the
18 existence of these agreements is in dispute, but my
19 eyeballing those agreements is not really controlling here.

20 Bavarian Nordic contends that Professor Mayer
21 provided technology to Dr. Bernard Moss, supposedly for
22 research purposes only. NIH strongly disputes that
23 characterization of it being for research purposes only.
24 Bavarian contends that its competitor, Acambis, thereafter
25 improperly obtained the technology from NIH by the hand of

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1 Dr. Moss.

2 There are documents that have been provided that
3 suggest that this was done under a material transfer
4 agreement dated 11/27/02, which includes Defendant's
5 agreement, that is, Acambis' agreement, to indemnify the
6 United States for any claim arising from its receipt of this
7 technology.

8 The agreement also contains Acambis' agreement not
9 to bring the United States into any lawsuit involving these
10 technology materials, and Bavarian Nordic has reason to
11 believe that Dr. Moss has a longstanding consulting
12 relationship with Acambis and has previously engaged in
13 providing Acambis with Plaintiff's confidential information.

14 Bavarian Nordic contends that Acambis has used
15 Bavarian's technology for a commercial advantage, and this is
16 all the essence of a lawsuit in the District of, I believe,
17 Delaware. But by way of deposition and production of
18 documents, Bavarian Nordic is seeking discovery on these
19 circumstances which led to Dr. Moss' receipt of the
20 technology and how it was provided to Acambis.

21 We certainly have a letter of August the 1st, 2006
22 where Dr. Kington, of NIH, advised Bavarian Nordic that it
23 had failed to comply with 45 CFR Part 2 in the issuance of
24 the subpoena. In that letter Dr. Kington noted that NIH did
25 not improperly provide the technology, that the subpoena was

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1 overly broad and sought privileged information without
2 further specificity and stated that the documents had been
3 previously provided in response to a FOIA request.

4 Dr. Moss also was prohibited from providing
5 testimony on the technology and contracted issues when he was
6 deposed in his individual capacity. That deposition occurred
7 on August 28th. Also present at the deposition were counsel
8 for the government, and Dr. Moss was prohibited from
9 answering certain questions, leaving Bavarian Nordic's
10 counsel with uncertainty as to what activities were conducted
11 by Dr. Moss as part of his duties at NIH and which were done
12 as part of any consulting activities on behalf of Acambis, if
13 such existed.

14 Finally, on September 1 we have this letter that we
15 have discussed at great length wherein Bavarian Nordic
16 narrowed the discovery request and the scope of the hope of
17 testimony from Dr. Moss. This was provided in an attempt to
18 demonstrate the relevance of the sought after information,
19 why it was not otherwise available and why disclosure was in
20 the best interest of NIH. And as of the time of the filing,
21 there was no indication that the government had provided any
22 response thereto, and I think we have heard a little bit
23 about that today.

24 I agree with the parties that this case is governed
25 by Comsat Corporation vs. NSF, a 4th Circuit 199 decision,

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1 and I believe that Comsat makes clear that in the Fourth
2 Circuit we are to follow the Administrative Procedures Act.
3 That Act also includes -- rather, the Comsat case also
4 includes the reference to a differential standard of review
5 to agency action, and we are looking at 5 USC 706's standard
6 of arbitrary and capricious conduct.

7 Let me put my hand on the section again where it
8 says it in 706. "That to the extent necessary to decision
9 and when presented, the reviewing court shall decide all
10 relevant questions of law, interpret constitutional and
11 statutory provisions and determine the meaning or
12 applicability or the terms of an agency action. The
13 reviewing court shall, 1) Compel agency action unlawfully
14 withheld or unreasonably delayed; and 2) Hold unlawful and
15 set aside agency action findings and conclusions found to be
16 arbitrary, capricious and abuse of discretion or otherwise
17 not in accordance with the law."

18 The parties have not made reference to the other
19 subparts, being b, c, d, e and f, and I don't take any issue
20 with their non-relevance.

21 But 45 CFR 2.3 empowers the NIH director to permit
22 testimony of employees or the disclosure of documents "based
23 on a determination that compliance would promote the
24 objectives of the department."

25 So, I take the time to look at the various factors,

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1 as did the Comsat Court, as did the Vioxx Court, in terms of
2 whether or not the decisions here are arbitrary and
3 capricious.

4 NIH says it produced documents under the FOIA Act
5 in response to a subpoena in a proceeding before the
6 International Trade Commission. Plaintiff contends that NIH
7 only produced documents reflecting communications between
8 Plaintiff and NIH, correspondence between Dr. Moss and
9 Professor Mayor and lab notes regarding NIH's research on the
10 technology.

11 The Plaintiff further states that nothing has been
12 produced which relates to the circumstances of NIH's
13 disclosure to Acambis and the requests have, thereafter, been
14 narrowed. On this prong I find in favor of Bavarian Nordic.

15 The availability of documents from other sources.
16 The Plaintiff claims that it has narrowed the request to seek
17 only internal NIH documents that are not available elsewhere.
18 NIH suggests that some of the documents are protected from
19 disclosure by privilege. No log has been provided, as would
20 be required under Rule 45, and I believe counsel have all
21 agreed that Rule 45 as further modified by the arbitrary and
22 capricious standard.

23 So, I won't touch so much upon the privilege
24 question, but the availability of all of these documents from
25 another source I don't think is true. I think there are

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1 documents that are internal to NIH and not otherwise
2 available from other places, which the Plaintiff has
3 satisfied his burden on that point and should be entitled to
4 those documents if all other points are in favor of Plaintiff
5 or if, in fact, the Plaintiff carries the day on the
6 balancing of factors here.

7 There is also a factor that I believe the Comsat
8 Court talked about; the indemnity relationship or whether or
9 not the Government has some exposure. And as a non-party,
10 NIH contends that it cannot defend its interests, and I think
11 through the course of discussion here that that interest
12 really is driven by its potential legal exposure. While not
13 in this case at present, it certainly may be down the road.

14 I have not heard any clear statement that the
15 government is beyond the powers of any potential plaintiff to
16 bring a lawsuit on these actions. Here there is the
17 indemnification, there is a covenant not to sue or something
18 to that effect by Acambis, but I do not find that the
19 government's interests are completely covered.

20 Another factor is whether an injustice will occur
21 if the government is not required to make a disclosure. I
22 don't have enough information on that prong to say whether an
23 injustice would occur. But the other balancing of interests
24 involved is that Plaintiff suggests that NIH violates its own
25 policy under 45 CFR 2.1(b) of maintaining strict

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1 impartiality, as it believes that Dr. Moss has been aligned
2 with Acambis and allegedly conveyed confidential information.

3 I don't know about the confidential information
4 that may have preceded this particular involvement, and I
5 don't know if the case has been proven, but it certainly is
6 an interest that the Plaintiff is moving forward on. That is
7 an important interest, the answer of which I have no way of
8 knowing.

9 But I would agree with the Plaintiff that there
10 would be no hardship for Dr. Moss to speak under oath again.
11 He has done so once, and there is no reason to believe that
12 such would impair or substantially impair the operations of
13 NIH.

14 To the extent that there is a concern about the
15 floodgates of litigation, I agree with the opinion writer in
16 Vioxx, although I do believe that there is some Fourth
17 circuit language to the contrary. The Plaintiff contends
18 that the Project Bioshield Act promotes a partnership between
19 the national defense and the private sector industry and the
20 government in this area and that intellectual property
21 protection is crucial to this effort.

22 That may be true. So that factor, if there is
23 such, weighs in Plaintiff's favor. And Plaintiff's cover
24 letter with the subpoena of July 24, 2006 noted that the
25 litigation was, in part, concern with the "safeguards that

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1 scientists rely on when they transfer innovative property to
2 other researchers in the hope of creating opportunities for
3 collaboration. These safeguards include assurances that the
4 materials will be used only for research purposes."

5 That is an important interest. Whether or not it
6 is subverted by the government's actions here is another
7 question, and to the extent that there were any concerns
8 about these requests being over broad, I believe that the
9 Plaintiff has sufficiently narrowed the scope in the face of
10 no further response from the NIH.

11 Assuming all of the representations of Bavarian
12 Nordic are true, and I do in large measure here, it is still
13 quite apparent to me that allowing Dr. Moss to testify would
14 more likely than not reveal evidence that is contrary to the
15 interests of NIH. There is the potential breach of
16 non-disclosure agreements. There is the potential complicity
17 with Acambis. There is potential tortious conduct, which is
18 not protected by sovereign immunity.

19 NIH's fears about facing a lawsuit for these very
20 reasons has been articulated in its letter to Plaintiff of
21 January 11th, 2006, when it was facing similar claims that
22 were then lodged before the International Trade Commission.
23 There is strong Fourth Circuit law in favor of the
24 government. The most meaningful case for the Plaintiff, of
25 course, is the Vioxx decision.

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1 I am, however, drawn back to the Motor Vehicle
2 decision. The Supreme Court made a ruling in Motor Vehicle
3 Manufacturer's Association vs. State Farm in 1983 which said
4 that the "scope of review under this arbitrary and capricious
5 standard is narrow and the court is not to substitute its
6 judgment. The agency must examine the relevant data and
7 articulate a satisfactory explanation, including a rational
8 connection between the facts found and the choice made."

9 "Normally the agency rule is arbitrary and
10 capricious if the agency relied on factors that Congress did
11 not intend or failed to consider an important aspect of the
12 problem or offered an explanation that runs counter to the
13 evidence or is too implausible."

14 Further, in the Maryland General Hospital case, 4th
15 Circuit of 2002, "The Court is to give substantial deference,
16 though not blind obedience to the action of the agency."

17 I don't find anything "arbitrary or capricious"
18 about the government's interest in protecting itself from
19 allegation of misconduct. There are very limited exceptions
20 to the Sovereign Immunity Doctrine, and the lawmakers have
21 intended that the government can elect to protect or, should
22 I say, prohibit disclosure under such circumstances.

23 Such an election has been made. Plaintiff's
24 motion, accordingly, is denied, as well as the request for
25 fees and expenses incurred.

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1 My judgment, my view, my ideas about government
2 transparency are completely irrelevant. Those who make the
3 law determine what, if anything, the government's obligations
4 are. And I think in this instance, while it may not be as
5 one would expect in the typical civil scenario where we are
6 expecting full disclosure on everything that is not
7 privileged, there are other interests to be afforded here,
8 and that is what the law attempts to get it.

9 Is it arbitrary? No. The government provides a
10 reason. Is it capricious and mean spirited and filled with
11 ill will? No. The government has articulated a reason.
12 Basically, self interest. Is it otherwise contrary to law?
13 Not at all. There is nothing in the actions of the
14 government.

15 Even though there is the quotation about the strict
16 impartiality and the reference to the Bioshield Act, I don't
17 find that either of those fly contrary to the position taken
18 by the government. So, as best as I can read it, I think
19 that the government's action is protected here. Not only as
20 to the testimony, but also as to the documents.

21 I suspect that this may not be the end of it, but
22 hopefully, you all have sufficient information to work from
23 and to take it to the next level. Any response further from
24 the -- I guess Plaintiff gets to go first.

25 MR. LUBITZ: Well, I would like a clarification,

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1 Your Honor. Are you denying the motion to compel both to the
2 documents and to the testimony?

3 THE COURT: Yes. Because both are governed by the
4 arbitrary and capricious question. If I analyze that
5 question appropriately, whether the government is not
6 providing these documents because it is not in their best
7 interests, or if they are not allowing the testimony to go
8 forward for the same reason, I think our discussion earlier
9 came back to even under Rule 45 that would be modified by
10 whether or not the government is acting in an arbitrary and
11 capricious way.

12 And since that is the standard that governs both, I
13 believe that their response, even though procedurally may be
14 faulty, it comes back to that analysis at the end of the day.

15 MR. LUBITZ: Okay. Well, I just reserve objection
16 on the record, because I think that there is a different
17 standard for documents and testimony. But we can take that
18 up. Thank you.

19 THE COURT: That is fair enough. Anything further
20 from the NIH?

21 MR. HOSKIN: No, Your Honor.

22 THE COURT: Okay. And, Mr. Dunn, I thank you again
23 for your measured silence.

24 MR. DUNN: All I can say, Your Honor, is that while
25 we would have enjoyed having the testimony and filed our own

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1 Tuhey request, we looked at the response and came to the same
2 conclusion that Your Honor did, that it was reasonable.

3 THE COURT: Okay. Well, I thank you all again for
4 your patience, and I wish you a good holiday season. Have a
5 good day.

6 (Whereupon, the telephone conference was
7 concluded.)

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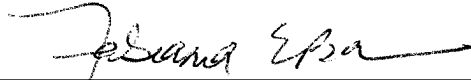
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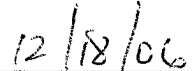
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C E R T I F I C A T E

I certify that the foregoing is a correct transcript from the electronic sound recording of the proceedings in the above-entitled matter.



Fabiana E. Barham
Transcriber



Date